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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/445,796	03/13/00	BRASSART	D P99.2625

HM12/0227
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EXAMINER	
AFREMOVVA, V	

ART UNIT	PAPER NUMBER
1651	9

DATE MAILED: 02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/445,796	Applicant(s) Brassart et al.
Examiner Vera Afremova	Group Art Unit 1651

Responsive to communication(s) filed on Nov 2, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-10 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 3, 4 and 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

... SEE OFFICE ACTION ON THE FOLLOWING PAGES ...

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DETAILED ACTION

Claims 1-10 are pending and under examination.

Priority

Receipt of foreign priority document filed in EPO on 7/05/1997 is acknowledged as related to PCT application PCT/EP98/04036. However, applicants have not complied with the requirements of 37 CFR 1.63(c), since the oath or declaration for the instant application does not acknowledge the filing of any foreign application. A new oath or declaration is required in the body of which the present application should be identified by application number and filing date.

Claim Rejections - 35 U.S.C. § 112

Claims 1-9 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 provide for the use of lactobacteria, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

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example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 4 is indefinite because it fails to point out amounts of lactobacteria. It is unclear whether the whole nutritional composition contains 10^7 - 10^{11} CFU (colony forming units) or whether the claimed amounts are intended per ml or per mg of the composition in the method of administration for increasing absorption of minerals.

All claims are indefinite with regard to the term "*lactobacilli*" as presently claimed. This is not correct Latin name of the genus *Lactobacillus* if only representatives of this genus are intended. And it is unclear whether this italicized term "*lactobacilli*" encompasses the use of all lactobacteria and bifidobacteria which are capable to adhere to intestinal cells, to acidify environment due to production of lactic acid and to promote absorption of minerals.

Deposit

Claim(s) 3 is rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism *Lactobacillus johnsonii* CNCM I-1225. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the

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microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37CFR 1.808.

Because Collection Nationale de Culture de Microorganisms (CNCM) has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions will be irrevocably removed upon issuance of the patent will overcome this rejection.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,494,664

[A] or by US 5,578,302 [B].

The claims are directed to a method for increasing absorption of minerals from the diet wherein the method comprises enterally administering to a mammal a nutritional composition which contains lactobacteria or bifidobacteria. Some claims are further drawn to the use of *Lactobacillus johnsonii* CNCM I-1225 in the method of administration of the nutritional composition. Some claims are further drawn to the use of lactobacteria in amounts 10^x7 to 10^x11 CFU in the method of administration of the nutritional composition. Some claims are further drawn to the use of milk products and/or milk hydrolysates in the nutritional composition in the method of administration.

US 5,494,664 [A] (col. 1, line 43-60 and col. 2, line 14) or US 5,578,302 [B] (abstract)

teaches a method for improving mammal health wherein the method comprises enterally administering to a mammal a nutritional composition which contains lactobacteria and/or bifidobacteria including *Lactobacillus johnsonii* CNCM I-1225 in amounts 10^x7 to 10^x11 CFU/g in nutritional composition in a form of yogurt or other milk-based product. The cited references are considered to anticipate the claimed invention because the cited method is one active step method comprising one step of enterally administering identical composition to identical patient as the claimed method. Consequently, the intended result as disclosed and as claimed is identical.

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Claim Rejections - 35 U.S.C. § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yaeshima [IDS-3-AR] and Yoshida [U].

The claims as explained above.

The cited references by Yaeshima [IDS-3-AR] (page 41) and Yoshida [U] (abstract) disclose a method for increasing absorption of minerals from the diet wherein the method comprises enterally administering to a mammal a nutritional composition which contains various species belonging to lactobacteria or bifidobacteria alone or with additional products such as dietary fibers (oligosaccharides or lactulose) and minerals (calcium, magnesium, etc.).

The referenced methods appear to be identical to the presently claimed method and are considered to anticipate the claimed invention since they are one active step methods of administering identical nutritional compositions with live lactobacteria or bifidobacteria alone or with additional products such as dietary fibers (oligosaccharides or lactulose) and minerals (calcium, magnesium, etc.) to identical patients for improving absorption of minerals. Consequently, the claimed method of administration appears to be anticipated by the cited references.

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In the alternative, even if the claimed method is not identical to the referenced methods with regard to particular microbial cultures in the nutritional composition intended for administration or with regard to some others unidentified characteristics, the differences between that which are disclosed and that which are claimed are considered to be so slight that the referenced methods are reasonably believed to produce identical effects with regard to absorption of minerals as it is taught by the cited references. Or substitution of one lactobacterium or bifidobacterium for another lactobacterium or bifidobacterium in the method of administration is likely to be substitution of equivalents. And, thus, the claimed method of administration would have been obvious to those of ordinary skill in the art within the meaning of U.S.C. 103. Therefore, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova, Art Unit 1651

February 21, 2001.



FRANCISCO PRATS
PRIMARY EXAMINER